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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/916,140

08/21/1997

MATTHEW P. SCOTT

CIBT-P04-203

2613

28120

7590

12/28/2001

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 12/28/2001

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

08/916,140

Applicant(s)

Scott

Examiner

Richard Schnizer

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Dec 14, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: Amendments broaden scope of claims from "agents for ameliorating" patched loss of function, to "agents which affect" patched signal transduction in any way. New search is required.

4. ☐ Applicant's reply has overcome the following rejection(s): _____
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: None
Claim(s) objected to: _____
Claim(s) rejected: 61-77
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other: _____

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ADVISORY ACTION

The request for reconsideration has been considered but does not place the application in condition for allowance.

At page 7 of the response, applicant traverses the rejection of claims 62 and 72-75 for containing new matter. Applicant argues that the specification provides support for the claimed invention, referring to several specific passages. This argument is unpersuasive because none of the passages provides literal support for a method in which patched loss of function is reversed by addition to cells having a patched loss of function phenotype of agents which do not cause production of functional patched.

At pages 8-11 of the response, Applicant traverses the rejection of claims 61-77 for lack of enablement. Applicant argues at page 8 that given the state of the art and the prophetic teachings in the specification that one of skill in the art could have practiced the invention to the full scope of the claims. Applicant relies for support WO 01/2644, published 4/19/01, asserting that this document shows that a compound was used to treat a BCC phenotype in skin punches from patched null mice. This is inaccurate. The study in question used cell punches from mice which were transgenic for a lac Z gene inserted into the ptc locus, but which had normal ptc function. See page 124, lines 22-26. For this reason WO 01/2644 is non-analogous art for claims 63-71, 76 and 77, which require cells with a patched loss of function, thus Applicant's arguments are unpersuasive with respect to these claims. Furthermore, when read in light of the

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specification, and in light of dependent claims 75 and 77, each of the rejected claims reads on a method of therapy of disorders characterized by patched loss-of-function. As indicated in Paper Nos. 16, and 25 the selection of agents to be tested in the claimed methods was problematic at the time of filing because the biochemical role of patched in cellular proliferation was not well understood. As a result, further research was required before potential agents could even be selected. See Pennisi Science 272: 1583-1584. Guidance in this regard in the specification is limited to the definition of "agents" as "preferably small organic compounds having a molecular weight of more than 50 and less than 2500 Daltons, and a non-limiting exemplary list of classes of molecules including peptides, saccharides, fatty acids, steroids, purines, and pyrimidines. Thus there is reason to doubt that the instant invention can be used to identify compounds which can modulate cell proliferation, and there is insufficient guidance as to what candidate compounds should be used in the method. In this respect, Applicant's reliance on post-filing art to traverse the rejection is unpersuasive. Five years lapsed between Pennisi's assertion that further research would be required to identify potential agents for *in vivo* use and the disclosure of a compound which shows some effect *ex vivo*. This does not serve as evidence that one of skill in the art could have relied on Applicant's disclosure of "small organic compounds having a molecular weight of more than 50 and less than 2500 Daltons" to identify active agents without undue experimentation.

For these reasons Applicant's arguments are insufficient to overcome the rejections.

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Crouch, can be reached at 703-308-1126. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Patsy Zimmerman whose telephone number is 703-308-8338.

Richard Schnizer, Ph.D.



**JAMES KETTER
PRIMARY EXAMINER**